

**REMARKS**

The foregoing amendment amends independent claims 1, 12, 30, 32, 46, 47 and 48. Claims 4, 25 and 49-50 are previously canceled. Claims 39-45 are withdrawn as a result of the prior election. Pending in the application are claims 1-3, 5-24, 26-48 and 51, of which claims 1, 12, 30, 32, 46, 47 and 48 are independent. The following comments address all stated grounds for rejection and place the presently pending claims, as identified above, in condition for allowance.

Independent claims 1, 12, 30, 32, 46, 47 and 48 are amended to positively recite that the one or more fluid interface ports are formed in the top wall of a separation channel. Support for this amendment may be found throughout the application as originally filed, at least, for example, in Figures 4A-4C and the accompanying text.

In addition, independent claims 1, 12, 30, 32, 46, 47 and 48 are amended to positively recite that the sample to be separated is directly injected into the separation medium through one or more of the virtual walls. Thus, the virtual wall serves as the entry for the sample into the separation medium. Support for this amendment may be found throughout the application as originally filed, at least, for example, in Figures 4A-4C and the accompanying text.

Furthermore, independent claims 1, 12, 30, 32, 46, 47 and 48 are amended to positively recite that the separation device is free of sample reservoirs and free of channels providing samples to be separated to the plurality of separation channels. Support for this amendment may be found throughout the application as originally filed, at least, for example, in Figure 3 and the accompanying text and on page 19, lines 3-5.

Independent claims 1, 12, 30, 32, 46, 47 and 48 also are amended to positively recite that a separation channel is a channel with ends that are connected to anode and/or cathode reservoirs and that the separation medium is a material with a property that samples in the medium are separated via application of an electric field across a channel that the medium fills. Support for these amendments may be found throughout the application as originally filed, at least, for example, on page 3, lines 28-34 and page 9, lines 25-27.

Amendment and/or cancellation of the claims is not to be construed as an acquiescence to any of the objections/rejections set forth in the instant Office Action, and was done solely to expedite prosecution of the application. Applicants reserve the right to pursue the claims as originally filed, or similar claims, in this or one or more subsequent patent applications.

### **35 U.S.C. § 112 Rejections**

Regarding the rejection of claims 1-3, 5-24, 26-38, 46-48 and 51 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, Applicants maintain that the argued definition of “co-planar” is appropriate. However, to expedite prosecution, Applicants have removed the recitation of “co-planar” from independent claims 1, 12, 30, 32, 46, 47 and 48.

### **35 U.S.C. § 103 Rejections**

In the Office Action, the Examiner rejects claims 1-3, 5-24, 26-38, 46-48 and 51 as being unpatentable over U.S. Patent No. 6,627,406 to Singh et al. (Office Action, page 5). Applicants submit that the claims distinguish patentably over the cited Singh reference.

The Examiner alleges that “undue weight cannot be given to the recitation of ‘separation’ channels or ‘separation’ medium” because “[s]pecifying an intended use, such as separation, does not structurally define the channels or medium.” Independent claims 1, however, recites that a separation channel is a structure with “a first end connected to the one or more anode reservoirs and a second end connected to the one or more cathode reservoirs.” Independent claims 12 and 46 also recite a separation channel with two ends connected to anode or cathode reservoirs or arrays of anode or cathode reservoirs. Independent claims 30, 32, 47 and 48 recite a separation channel with one end connected to an anode or cathode reservoir or an array of anode or cathode reservoirs. Applicants submit that since the claims positively define structure of the channels, channels that do not have ends connected to anode or cathode reservoirs cannot be considered to read on the instant “separation channels.”

In addition, independent claims 1, 12, 30, 32, 46, 47 and 48 recite that the separation medium is “a material that effects separation of a sample in the separation medium via

application of an electric field across the plurality of separation channels.” Applicants submit that since these claims positively define structure of the medium, mediums that are not used to “effect separation of a sample in the separation medium via application of an electric field across the plurality of separation channels” cannot be considered to read on the instant “separation medium.”

Independent claims 1, 12, 30, 32, 46, 47 and 48 specify that the fluid interface ports is formed in the top wall of the separation channels. In contrast, Singh’s fluid interface ports 612 are not formed in the top wall of a separation channel. Instead, Singh’s ports are formed in a channel that is not connected to anode or cathode reservoirs. The Examiner alleges that “it would have been obvious to provide electrodes to the reservoirs ... because it would provide the ability to manipulate the fluids in the device electrokinetically.” Applicants respectfully disagree. Singh’s Figure 7A illustrates a system including three kinds of channels. Channel 706 includes a solution. The solution is distributed from central reservoir 702 through channel 706 to zone enclosures 704 that include a liquid. The solution and the liquid react, forming a reaction mixture (Singh, col. 29, lines 27-43). Channel 706 is not a separation channel since it does not have ends connected to either an anode or cathode reservoir. Channels 716 and 720 and reservoirs 704, 718 and 732 form an electrokinetic channel. However, this channel is used to move particles, not to separate samples (Singh, col. 29, lines 49-53). Thus, channels 716 and 720 are not separation channels filled with separation mediums. Channel 724 includes a “sieving polymer to separate components of different mobilities” and has ends connected to electrodes 736 and 738. Thus, Singh’s channel 724 may be read on Applicants’ separation channel. However, Singh does not disclose, teach or suggest that channel 724 includes fluid interface ports formed in the top wall of the separation channel. Since Singh explicitly states where electrodes would be placed in a system and for what purpose, Applicants submit that it would not be reasonable to add electrodes to additional reservoirs since the channels 706 are not meant to be manipulated electrokinetically. Thus, Singh does not disclose, teach or suggest Applicants’ fluid interface ports.

Furthermore, Singh does not disclose, teach or suggest that the sample to be separated is injected into the separation medium via one or more virtual walls or that the device is free of sample introduction structures such as sample reservoirs and sample channels, as recited in

independent claims 1, 12, 30, 32, 46, 47 and 48. Instead, Singh uses the prior art method of using channel 720 to introduce a sample to be separated into separation channel 724.

Accordingly, Singh does not disclose, teach or suggest each and every feature of independent claims 1, 12, 30, 32, 46, 47 and 48.

Applicants also maintain that the combinations of the Heller reference (WO 99/64850 or US 6,846,398), the McCormick reference (US 6,613,211) or the Amigo reference (US 5,935,401) fail to render independent claims 1, 46, 47 and 48 obvious.

The Heller reference discusses separation channels, but the separation channels are fed samples via the shared injection channel. The injection channel is not a separation channel because it is not filled with a medium that effects separation of the sample when an electric field is applied across it. Instead, the injection channel is filled with a medium that moves the sample to the separation channels. Thus, Heller does not disclose, teach or suggest at least the fluid interface ports formed in a top wall of a separation channel or a device that is free of sample introduction structures such as sample reservoirs and sample channels, as recited in independent claims 1, 46, 47 and 48.

McCormick and Amigo do not remedy the shortcomings of Heller with respect to independent claims 1, 46, 47 and 48. McCormick discusses a microfluidic system for moving entities, not separating entities. In McCormick, reservoirs are used for introducing samples to be moved. Amigo discusses methods of manufacturing electrophoretic chambers. Thus, neither McCormick nor Amigo discloses or suggests a separation device with fluid interface ports formed in a top wall of a separation channel or a separation device that is free of sample introduction structures such as sample reservoirs and sample channels. Accordingly, Heller, McCormick, and Amigo, alone or in any reasonable combination, do not disclose, teach or suggest each and every feature of claims 1, 46, 47 and 48.

Applicants also maintain that the combination of Heller, Bjornson (US 6,284,113), and either the McCormick or Amigo references fail to render independent claim 12 obvious.

As discussed above, the combination of Heller and McCormick or Amigo fail to disclose, teach or suggest a separation device with fluid interface ports formed in a top wall of a

separation channel or a separation device that is free of sample introduction structures such as sample reservoirs and sample channels. Bjornson does not remedy the shortcomings of Heller, McCormick and Amigo with respect to independent claim 12. Bjornson discusses structures for transferring elements. Bjornson also illustrates in Figure 5 the use of a channel 120 to feed another channel 122. Bjornson is silent with respect to fluid interface ports formed in a top wall of a separation channel or a separation device that is free of sample introduction structures such as sample reservoirs and sample channel. Thus, Heller, Bjornson, and McCormick or Amigo, alone or in any reasonable combination, do not disclose, teach or suggest each and every feature of claim 12.

Applicants also maintain that the combinations of the Simpson reference (US 6,143,152) and the Howitz reference (US 5,730,187) fail to render independent claims 1, 12, 30, 32, 46, 47 and 48 obvious. The Examiner acknowledges that the Simpson reference does not explicitly disclose a device including fluid interface ports formed in the top wall of the separation channels. However, the Examiner alleges that the Howitz reference discloses these features. Applicants respectfully disagree.

The Howitz reference does not disclose, teach or suggest a separation device having a separation channel having a first side wall opposing a second side wall and a top wall opposing a bottom wall, wherein the first side wall and the second side wall each have a top end and a bottom end, and the top wall abuts the top ends of the first side wall and the second side wall and the bottom wall abuts the bottom ends of the first side wall and the second side wall each having a top end and a bottom and fluid interface ports formed in the top wall of the separation channel. Instead, Howitz discusses that the flow of the channel 7 must be stopped by a channel stop 8, and the flow of the channel 7 must be redirected to a fluid microdiode 1 that is placed on top of the channel and aligned with the channel so that the flow of the channel goes through the fluid microdiode device. Howitz acknowledges that the fluid microdiode device is separate from the channel. Thus, Howitz does not disclose, teach or suggest fluid interface ports formed in a top wall of the separation channel.

Applicants further submit that one skilled in the art would not combine Howitz and Simpson to apply fluid microdiodes to the top of the separation channels of Simpson because

separation channels should be flat for reliable performance. The Examiner alleges that the “sample and waste reservoirs” of Simpson may simply be replaced with “holes through the sidewall to serve as a fluid port,” as taught by Howitz. Applicants submit, however, that Howitz does not disclose, teach or suggest “holes through a sidewall of a channel.” Instead, Howitz suggests use of a fluid microdiode. The two are not equivalent. The fluid microdiode is a structure including a channel for delivering samples to another channel. Thus, Applicants submit that the Examiner is using impermissible hindsight to reconstruct the teachings of the present application from the cited references.

Bjornson does not remedy the shortcomings of Simpson and Howitz, with respect to independent claim 9 since Bjornson does not disclose, teach or suggest a device including fluid interface ports formed in the top wall of the separation channels.

Sundberg (US 6,090,251) does not remedy the shortcomings of Simpson and Howitz, with respect to claims 37 and 51, because Sundberg also does not disclose, teach or suggest a device including fluid interface ports formed in the top wall of the separation channels.

Claims 2-3, 5-11 and 51 depend directly or indirectly from and incorporate all of the elements of claim 1, so claims 2-3, 5-11 and 51 are patentable for at least the same reasons as set forth above for claim 1. Claims 13-24 and 26-29 depend directly or indirectly from and incorporate all of the elements of claim 12, so claims 13-24 and 26-29 are patentable for at least the same reasons as set forth above for claim 12. Claim 31 depends directly from and incorporates all of the elements of claim 30, so claim 31 is patentable for at least the same reasons as set forth above for claim 30. Claims 33-38 depend directly or indirectly from and incorporate all of the elements of claim 32, so claims 33-38 are patentable for at least the same reasons as set forth above for claim 32.

**CONCLUSION**

In view of the above arguments and amendments, Applicants believe that the presently pending rejections have been overcome and the presently pending claims are allowable. Should Examiner find a telephone call would be helpful, please do not hesitate to contact us.

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Respectfully submitted,

Electronic signature: /David R. Burns/  
David R. Burns  
Registration No.: 46,590  
LAHIVE & COCKFIELD, LLP  
One Post Office Square  
Boston, Massachusetts 02109-2127  
(617) 227-7400  
(617) 742-4214 (Fax)  
Attorney/Agent For Applicants